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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,887	10/12/2005	Villoo Morawala Patell	20049.1USWO	4453

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,887	PATELL, VILLOO MORAWALA	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-20 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-20 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection on October 28, 2008. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 8, 2008 has been entered.

Claims 1-16, 21-22 and 26-28 are cancelled.

Claims 17-20 and 23-25 are pending and are examined on merits in this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Specification

The amendment filed September 8, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the data in the table are not disclosed in the specification, nor is the numerical value of 30-95%. Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant maintains that the amendment does not introduce new matter since the data is derived from Fig. 1a (reply page 5).

Applicant's arguments are unpersuasive, as the data and the percentages are not depicted in Fig. 1a, or elsewhere in the specification as filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claims 23-24 require a transgenic rice variety produced by the method according to claim 17 that produces 30-95% increase in superoxide dismutase (SOD) activity. This subject matter does not find support in the specification as filed, and thus constitutes new matter.

Applicant's arguments filed September 8, 2008 have been fully considered but they are not persuasive.

Applicant points out that the specification has been amended to include data that clearly describes the level of increase in SOD activity of the transgenic rice variety as compared to non-transgenic plants, and Applicant maintains that since the data is derived from Fig. la, the submission of the data does not constitute new matter (reply page 5).

The Examiner maintains that both the claims and the amendment to the specification introduce new matter, as Fig. 1a does not support these amendments. With regard to Fig. 1a, the Examiner maintains that Fig. 1a shows only a graphic representation of the levels of SOD activity in TP309, Salween 2 and Godawari 8. (Fig. 1a and page 2 of the specification)

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that rice varieties Godavari 8 and Salween 2 are required to practice the claimed invention. As such they must be readily available, or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If they are not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the rice varieties. In the instant case it is not apparent whether rice varieties Godavari 8 and Salween 2 are both known and readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained.

If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see 37 CFR 1.809):

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23-24 are indefinite in the recitation of "30-95% increase in superoxide dismutase (SOD) activity, as increase is a relative term that lacks a comparative basis.

Claim Rejections - 35 USC § 103

Claims 17-20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Salt tolerance of transgenic rice overexpressing yeast mitochondrial Mn-SOD in chloroplasts. Plant Science. 1999. 148: 131-138) in view of Bowler et al. (European Patent Publication No. EP 0359617A2, Published March 21, 1990, Applicant's IDS), Nayak et al. (Transgenic elite indica rice plants expressing CryIAc delta-endotoxin of *Bacillus thuringiensis* are resistant against yellow stem borer (*Scirpophaga incertulas*). Proc Natl Acad Sci U S A. 1997 Mar 18;94(6):2111-6), Verdaguer et al. (Isolation and expression in transgenic tobacco and rice plants, of the cassava vein mosaic virus (CVMV) promoter. Plant Mol Biol. 1996 Sep;31(6):1129-39), and Davuluri et al. (Oxidative stress management-targeting MnSOD to the chloroplast. Meeting Abstract. Plant Biology (Rockville), (1999) Vol. 1999, pp. 103. print. Meeting Info.: Annual Meeting of the American Society of Plant Physiologists. Baltimore, Maryland, USA. July 24-28, 1999. American Society of Plant Physiologists (ASPP)).

The claims are drawn to a method for producing a transgenic Indica rice variety comprising: a. Constructing an expression vector for plant transformation that comprises a

Cassava vein mosaic virus (CVMV) promoter, a Manganese superoxide dismutase (MnSOD) coding sequence derived from *Nicotiana Plumbaginifolia* L., and a Pea ribulose-1-5-bisphosphate carboxylase small subunit transit peptide coding sequence, wherein the promoter, the transit peptide coding sequence and the MnSOD coding sequence are operably linked, and wherein said MnSOD coding sequence is further operably linked to a NOS terminator; b. Transforming rice calli of said indica rice variety with the vector constructed in step (a); and c. Regenerating the transformed calli into mature transgenic plants of said rice variety, wherein the transgenic rice variety produced by the method produces 30-95% increase in superoxide dismutase (SOD) activity, and wherein the transgenic plants display increased yield as compared to that of non-transgenic plants under environmental stress conditions, increased tolerance as compared to that of non-transgenic plants to pathogen attack, and play a role in the food industry by increasing a shelf life of said rice variety as compared to that of non-transgenic plants.

Tanaka et al. teach making a transgenic plant cell of Japonica rice with increased superoxide dismutase production, comprising transformation of said plant cell with a DNA construct, comprising a 35S CaMV promoter operably linked with a yeast SOD coding sequence which is operably linked with a NOS terminator. The 5' end of the SOD coding sequence is operably linked with a nucleotide sequence encoding a glutamine synthase chloroplast transit peptide signal. The transgenic plant cells are regenerated to obtain a mature transgenic plant of rice comprising said DNA construct. The transgenic plants also exhibited higher levels of superoxide dismutase production. The reference further teaches that said transgenic plants also exhibited increased tolerance to environmental stresses, and displayed higher yield under said environmental stress conditions. See in particular, page 131, abstract; page 132, materials and

methods; page 134, figure 3; page 135, figures 4-6; page 136, figure 7. The reference also teaches that the transgenic rice plants exhibited more than 1.5 fold (means greater than 30%) increase in Mn-SOD activity under NaCl stress. While Tanaka et al. do not explicitly teach increased tolerance to pathogen attack or increased shelf life of their rice variety, Tanaka et al. need not explicitly teach these limitations in order to render the claimed invention obvious, because these properties are a consequence of the method of manufacture of the transgenic plants (i.e. transformation with the recited expression vector), and are thus inherent to the method and to the plants produced by the method.

Tanaka et al. do not teach the transformation of Indica rice, or a MnSOD coding sequence derived from *Nicotiana Plumbaginifolia* L., or a Pea ribulose-1-5-bisphosphate carboxylase small subunit transit peptide coding sequence, or a Cassava vein mosaic virus (CVMV) promoter.

Nayak et al. teach a method for producing a transgenic Indica rice variety comprising: a. Constructing an expression vector for plant transformation that comprises a promoter, a CryIAc delta-endotoxin coding sequence derived from *Bacillus thuringiensis*, wherein the promoter and the CryIAc delta-endotoxin coding sequence are operably linked, and wherein the CryIAc delta-endotoxin coding sequence is further operably linked to a NOS terminator; b. Transforming rice calli of said indica rice variety with the vector constructed in step (a); and c. Regenerating the transformed calli into mature transgenic plants of said rice variety (page 2111 column 2 second full paragraph through page 2112 column 2 second full paragraph).

Bowler et al. teach a method of making a transgenic plant cell of *Nicotiana plumbaginifolia* with increased superoxide dismutase production, comprising transformation of

said plant cell with a DNA construct, which comprises a 35S CaMV promoter, operably linked with a nucleotide sequence encoding a superoxide dismutase derived from *Nicotiana plumbaginifolia L.*, and wherein, the 5' end of said superoxide dismutase coding sequence is operably linked with a nucleotide sequence encoding a pea ribulose-1-5-bisphosphate carboxylase transit peptide sequence, and wherein the 3' end of said superoxide dismutase sequence is further operably linked to a NOS terminator. The transgenic plant cells were regenerated to obtain a mature transgenic plant comprising said DNA construct. The transgenic plants also exhibited higher levels of superoxide dismutase production. The reference further teaches that said transgenic plants also exhibited increased tolerance to environmental stresses. The reference also teaches that increased SOD production in a plant cell results in increased resistance to pathogen attack. See in particular, page 2, lines 1-35; page 3, lines 50-60; page 4, lines 20-38, lines 63-65; page 5, lines 1-59; page 6, lines 5-24 and 39-59; page 8, line 61 to line 50 of page 10; page 11, lines 5-15; page 12, line 1 to page 13, line 45; page 16, line 49 to page 17, line 15. The reference also teaches that SOD activity was doubled (which is greater than 30%) in the transgenic plants overexpressing MnSOD (see page 11, lines 55-56).

Verdaguer et al. teach a method for producing a transgenic Japonica rice variety comprising: a. Constructing an expression vector for plant transformation that comprises a cassava vein mosaic virus (CVMV) promoter, a uidA coding sequence, wherein the promoter and the uidA coding sequence are operably linked, and wherein the coding sequence is further operably linked to a NOS terminator; b. Transforming rice calli of said rice variety with the vector constructed in step (a); and c. Regenerating the transformed calli into mature transgenic plants of said rice variety (page 1130 column 1 last paragraph through page 1131 column 2; page

1136 Figure 6; page 1137 Figure 7; see also Li et al. An improved Rice transformation system using the biolistic method. Plant Cell Rep. 1993. 12: 250-255, cited by Verdaguer et al.).

Davuluri et al. teach transforming rice calli with a pGV2 plasmid vector comprising a MnSOD cDNA cloned downstream of a CVMV promoter and a chloroplast targeting peptide followed by a NOS terminator. Davuluri et al. also teach transgenic rice plants transformed with said vector that produce the native engineered protein and in which the native engineered protein is localized in the chloroplast. Davuluri et al. additionally teach that the generation of superoxide radicals in the chloroplast is high during stress conditions, and that by targeting MnSOD to the chloroplast, the capacity to scavenge radicals can be increased.

Given the teachings of Tanaka et al. that transgenic rice plants having increased superoxide dismutase activity and increased tolerance to environmental stresses and higher yield under said environmental stress conditions can be made by transformation with a vector comprising a MnSOD coding sequence derived from yeast, a CaMV promoter and a chloroplast transit peptide coding sequence followed by a NOS terminator, given the teachings of Bowler et al. that transgenic tobacco plants having increased superoxide dismutase activity and increased tolerance to environmental stresses including increased resistance to pathogen attack can be made by transformation of tobacco with a vector comprising a MnSOD coding sequence derived from *Nicotiana plumbaginifolia L.*, a CaMV promoter and a pea ribulose-1-5-bisphosphate carboxylase transit peptide coding sequence followed by a NOS terminator, and given the teachings of Davuluri et al. that transgenic rice plants having increased chloroplast localized superoxide dismutase can be made by transformation of an unspecified rice variety with a vector comprising a MnSOD coding sequence of unspecified origin, a CVMV promoter and a

chloroplast targeting peptide of unspecified origin followed by a NOS terminator, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to transform any rice variety amenable to transformation, such as Indica rice as taught by Nayak et al., with a vector comprising a promoter, MnSOD coding sequence, a transit peptide coding sequence and a NOS terminator sequence, including a vector comprising a CVMV promoter, MnSOD coding sequence derived from *Nicotiana plumbaginifolia L.*, a pea ribulose-1-5-bisphosphate carboxylase transit peptide coding sequence and a NOS terminator sequence. One skilled in the art would have been motivated to do so in order to increase the stress tolerance of the plants as compared to the nontransformed variety. One skilled in the art would have had a reasonable expectation of success, given the success of Tanaka et al., Nayak et al., Bowler et al., Verdaguer et al. and Davuluri et al. in producing transgenic plants, including transgenic rice and Indica rice plants, that express the desired coding sequence, given the success of Tanaka et al., Bowler et al. and Davuluri et al. in producing transgenic plants, including transgenic rice plants, that express MnSOD targeted to the chloroplast, and given the success of Tanaka et al. and Bowler et al. in producing transgenic plants, including transgenic rice plants, that have increased stress tolerance. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC